Pharm Risk Approach Plan

Today

Timeline: 2020 | 2021 | 2022 | 2023 | 2024 | 2025

Start 10/2/19

High LxC 8/17/09 – 9/30/24

Mid LxC: Requires Mitigation 9/30/24 - 9/30/25

9/30/25

Countermeasure Options | Medication Characterization & Prioritization | Data Mining & Synthesis

HRR Gap: research logic description

New ECF versions based on evidence update and new conditions

Pharm-201: Exploration Candidate Formulary (ECF) v1.0

Pharm-201: ECF 2.0

Pharm-201: ECF 3.0

Pharm-201: ECF 3.x

Pharm-201: ECF 4.0

Pharm-101: Perform market analysis of packaging/storage options

◆ ExMC Decisions for Study Arms

Pharm-301: Define a process for assigning medications to colors on the stoplight chart.

◆ KDP Acceptance of Process

Pharm-301: ECF 1.0 Stoplight-Baseline ECF v1.0 Stoplight Chart

Pharm-301: ECF 2.0 Stoplight

Pharm-301: ECF 3.0 Stoplight

Pharm-301: ECF 3.x Stoplight

Pharm-301: ECF 4.0 Stoplight

◆ KDP Study Medication Selector

Flight Study Augmentation?

Pharm-401: Further study the safety and effectiveness of medications determined to be yellow on the most current version of the Stoplight Chart (concurrent with gaps Pharm-201 and Pharm-301). Also consider interaction with packaging/storage from gap Pharm-101.

⬢ Propose Risk Closure

External Deliverables

* This one-pager depicts strategy for only the stability portion of the pharm risk. PK/PD and pharmacogenomics strategy is forthcoming.

Maturation

Exploration Formulary
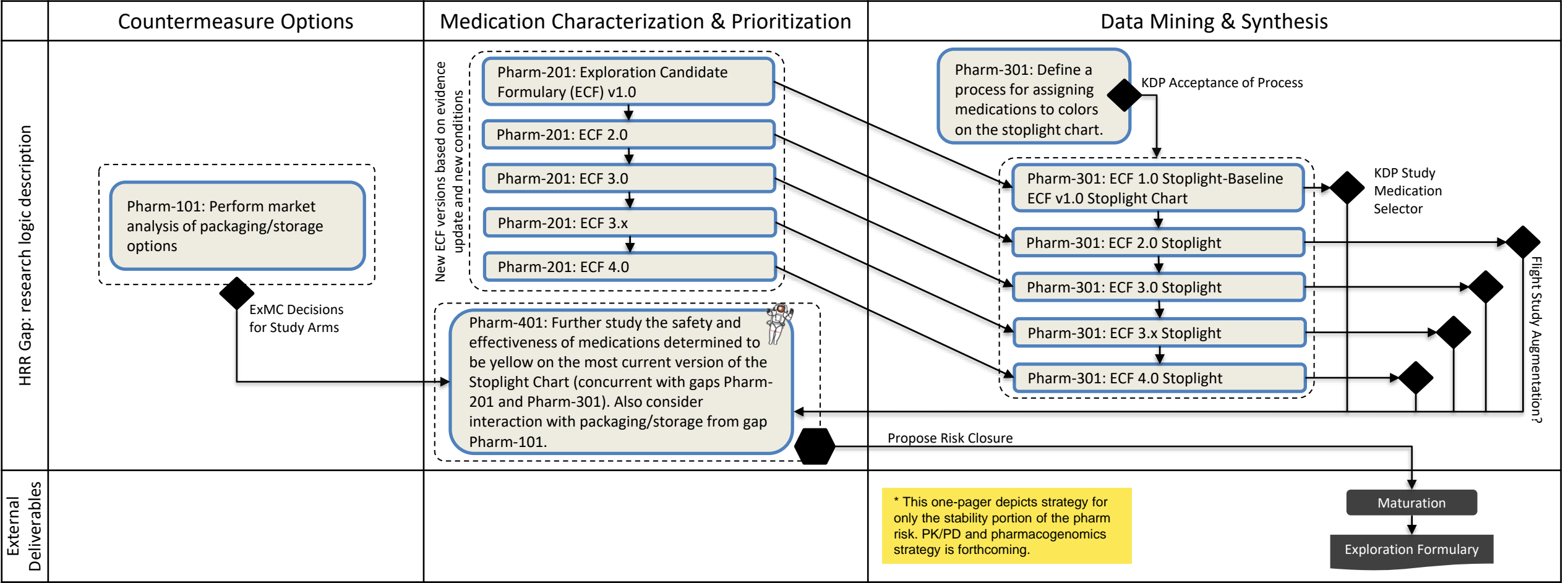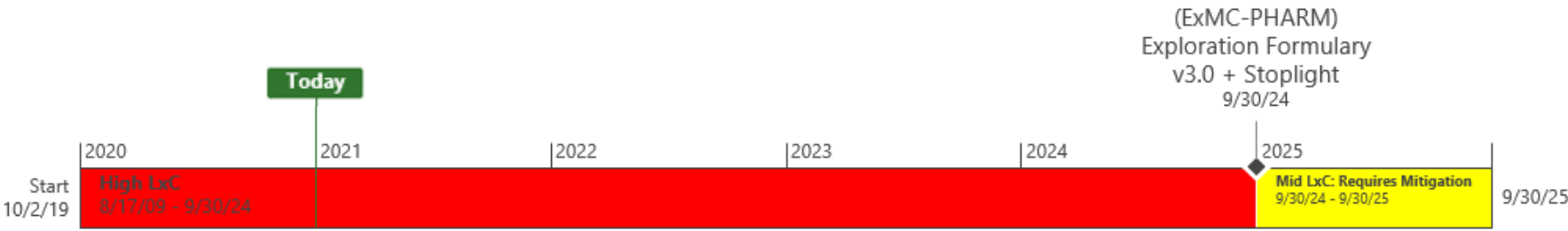

Note: Milestone (◆) and Gap Closures (⬢) are Program reviews with defined entry/exit criteria.

Legend: 🔵 Analog | 🧑‍🚀 Flight environment | ✖ Cross Element Integration | 🔴🟢🟡 Anticipated PRR Color Change